

(2) *For products containing bismuth subsalicylate identified in §335.10(a).* (i) The following shall appear in accordance with §201.66(c)(5)(ii) of this chapter.

(A) The Reye's syndrome warning in §201.314(h) of this chapter.

(B) "Allergy alert: Contains salicylate. Do not take if you are [bullet] allergic to salicylates (including aspirin), [bullet] taking other salicylate products".

(ii) "Do not use if you have [bullet] an ulcer [bullet] a bleeding problem".

(iii) "Ask a doctor or pharmacist before use if you are taking any drug for [bullet] anticoagulation (thinning the blood) [bullet] diabetes [bullet] gout [bullet] arthritis".

(iv) "When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur".

(v) "Stop use and ask a doctor if [bullet] symptoms get worse [bullet] ringing in the ears or loss of hearing occurs [bullet] diarrhea lasts more than 2 days".

(3) *For products containing kaolin identified in §335.10(b).* (i) "Ask a doctor or pharmacist before use if you are taking any other drugs. Try to use at least 3 hours before or after taking any other drugs."

(ii) "Stop use and ask a doctor if [bullet] symptoms get worse [bullet] diarrhea lasts more than 2 days".

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing any ingredient identified in §335.10.* The labeling states "[bullet] drink plenty of clear fluids to help prevent dehydration caused by diarrhea".

(2) *For products containing bismuth subsalicylate identified in §335.10(a).* The labeling states "[bullet] adults and children 12 years and over:" 525 milligrams "every 1/2 to 1 hour, or" 1,050 milligrams "every hour as needed [bullet] do not exceed" 4,200 milligrams "in 24 hours [bullet] use until diarrhea stops but not more than 2 days [bullet] children under 12 years: ask a doctor".

(3) *For products containing kaolin identified in §335.10(b).* The labeling states "[bullet] adults and children 12 years and over:" 26.2 grams "after each loose

stool [bullet] continue to take every 6 hours until stool is firm but not more than 2 days [bullet] do not exceed" [262 grams] "in 24 hours [bullet] children under 12 years of age: ask a doctor".

(e) *Products that meet the criteria established in §201.66(d)(10) of this chapter.* The information described in §201.66(c) of this chapter shall be printed in accordance with the following specifications.

(1) The labeling shall meet the requirements of §201.66(c) of this chapter except that the information in §201.66(c)(3) of this chapter may be omitted, and the information in §201.66(c)(5) and (c)(6) of this chapter may be presented as follows:

(i) The words "Contains salicylate." may be omitted from the warning in §335.50(c)(2)(i)(B).

(ii) The subheading "When using this product" in §335.50(c)(2)(iv) may be omitted.

(iii) The words "continue to" may be omitted from the directions in §335.50(d)(3).

(2) The labeling shall be printed in accordance with the requirements of §201.66(d) of this chapter except that any requirements related to §201.66(c)(3) of this chapter and the bullet in the warning in §335.50(c)(1)(i) may be omitted.

[68 FR 18881, April 17, 2003, as amended at 69 FR 26302, May 12, 2004]

PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 52 FR 15892, Apr. 30, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 336.1 Scope.

(a) An over-the-counter antiemetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 336.3 Definition.

As used in this part:

Antiemetic. An agent that prevents or treats nausea and vomiting.

Subpart B—Active Ingredients

§ 336.10 Antiemetic active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § 336.50(d):

- (a) Cyclizine hydrochloride.
- (b) Dimenhydrinate.
- (c) Diphenhydramine hydrochloride.
- (d) Meclizine hydrochloride.

Subpart C—Labeling

§ 336.50 Labeling of antiemetic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antiemetic.”

(b) *Indications.* The labeling of the product states the following under the heading “Indications,” “For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings:”

(1) *For products containing any ingredient identified in § 336.10—*(i) *When labeled for use in adults and for those products that can be and are labeled for use in children under 12 years of age.* “Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

(ii) *For those products that can be and are labeled only for children under 12 years of age.* “Do not give this product to children who have a breathing problem such as chronic bronchitis or who have glaucoma, without first consulting the child’s doctor.”

(2) *For products containing cyclizine hydrochloride identified in § 336.10(a).* “Do not give to children under 6 years of age unless directed by a doctor.”

(3) *For products containing dimenhydrinate identified in § 336.10(b).* “Do not give to children under 2 years of age unless directed by a doctor.”

(4) *For products containing diphenhydramine hydrochloride identified in § 336.10(c).* “Do not give to children under 6 years of age unless directed by a doctor.”

(5) *For products containing meclizine hydrochloride identified in § 336.10(d).* “Do not give to children under 12 years of age unless directed by a doctor.”

(6) *For products containing cyclizine hydrochloride identified in § 336.10(a) or meclizine hydrochloride identified in § 330.10(d).* “May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.”

(7) *For products containing dimenhydrinate identified in § 336.10(b) or diphenhydramine hydrochloride identified in § 336.10(c).* “May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take